The Florida Senate

COMMITTEE SUBSTITUTE ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Health Regulation Committee

BILL:	CS/SB 2272
INTRODUCER:	Health Regulation Committee and Senator Fasano and others
SUBJECT:	Pain Management
DATE:	March 27, 2010 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Stovall	Wilson	HR	**Fav/CS**
2.			CJ	
3.			HA	
4.			WPSC	
5.				
6.				

Please see Section VIII. for Additional Information:

A. COMMITTEE SUBSTITUTE.....	X	Statement of Substantial Changes
B. AMENDMENTS.....		Technical amendments were recommended
		Amendments were recommended
		Significant amendments were recommended

I. Summary:

This committee substitute modifies and enhances the regulation of pain management and pain-management clinics in Florida.

A practitioner who practices at a pain–management clinic is required to maintain control of his or her prescription blanks and any other method used for prescribing controlled substances for pain medication and report the theft, loss, or breach of these instruments to the Department of Health (Department). Only a medical physician or osteopathic physician may dispense any medication, including a controlled substance, on the premises of a pain–management clinic. Effective July 1, 2012, only a medical physician or osteopathic physician who has completed a pain medicine fellowship or pain medicine residency, or is a pain medicine specialist may practice in a pain-management clinic. A prescribing practitioner must notify the applicable board upon terminating his or her employment with a pain–management clinic.

The committee substitute provides for exceptions concerning the Department obtaining patient consent for release of patient records and authorizes the Department to obtain patient records without a subpoena from a pain–management clinic under certain conditions.

The committee substitute sets the venue for a challenge to, and enforcement of, subpoenas and orders related to the Department's regulation of health professions and occupations.

The committee substitute provides for additional exemptions to the registration requirements for a pain–management clinic including a clinic that: is owned by a publicly held corporation, is affiliated with an accredited medical school, does not prescribe or dispense controlled substances for the treatment of pain, or is owned by a corporate entity which is exempt from federal taxation as a charitable organization.

As a part of registering a pain–management clinic, a designated physician must be identified and certain responsibilities are assigned to the designated physician. The committee substitute provides additional grounds for disciplinary action against a licensee who serves as the designated physician of a pain–management clinic.

The committee substitute also authorizes the Department to deny an application to register a pain–management clinic, revoke or suspend a registration, or impose an administrative fine for various offenses or conditions. Additional requirements for operating a pain–management clinic are enumerated in the committee substitute.

The committee substitute establishes additional criminal violations related to:
- Knowingly operating, owning, or managing a nonregistered pain–management clinic that is required to be registered, which is a felony of the third degree; and
- Knowingly prescribing or dispensing, or causing to be prescribed or dispensed, controlled substances in a nonregistered pain–management clinic that is required to be registered, which is a misdemeanor of the first degree.

The Department is required to adopt rules addressing, but not limited to, what constitutes practice by a designated physician at the pain–management clinic for which the physician has assumed responsibility. The Boards of Medicine and Osteopathic Medicine are required to adopt a rule establishing the maximum number of prescriptions for certain controlled substances that may be written at a pain–management clinic daily.

This committee substitute substantially amends the following sections of the Florida Statutes: 456.037, 456.057, 456.069, 456.071, 456.072, 458.309, 458.327, 459.005, and 459.013.

This committee substitute creates the following sections of the Florida Statutes 458.3265 and 459.0137.

II. Present Situation:

Pain–Management Clinics

In 2009,[1] the Legislature required all privately owned pain–management clinics, which includes clinics, facilities, or offices, that advertise for any type of pain–management services or employ a physician or osteopathic physician who is primarily engaged in the treatment of pain by prescribing or dispensing controlled substance medications to register with the Department by

[1] See sections 3 and 4 of Chapter 2009-198, Laws of Florida (L.O.F.).

January 4, 2010.[2] Facilities licensed under ch. 395, F.S., i.e., hospitals, ambulatory surgical centers, or mobile surgical facilities, or clinics in which a majority of the physicians provide surgical services in the clinic are exempt from this registration requirement.

Approximately 940 pain–management clinics have registered with the Department since the law went into effect.[3]

The current law does not limit who may own a pain–management clinic. However, also during the 2009 Session, the Legislature enacted s. 456.0635, F.S.,[4] which, among other things, requires the Department to refuse to register a pain–management clinic if any principal, officer, agent, managing employee, or affiliated person of the applicant has been:

- Convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under ch. 409, F.S., related to social and economic assistance, ch. 817, F.S., related to fraudulent practices, ch. 893, F.S., related to controlled substances, 21 U.S.C. ss. 801-970, related to the federal controlled substances act, or 42 U.S.C. ss. 1395-1396, related to Medicare and Medicaid, unless the sentence and any subsequent period of probation for such conviction or pleas ended more than 15 years prior to the date of the application;
- Terminated for cause from the Florida Medicaid program pursuant to s. 409.913, F.S., unless the applicant has been in good standing with the Florida Medicaid Program for the most recent 5 years; or
- Terminated for cause, pursuant to the appeals procedures established by the state or Federal Government, from any other state Medicaid program or the federal Medicare program, unless the applicant has been in good standing with a state Medicaid program or the federal Medicare program for the most recent 5 years and the termination occurred at least 20 years prior to the date of the application.

An allopathic physician or osteopathic physician may not practice in a pain–management clinic that is required to be registered but is not registered.[5] Each clinic location must be registered separately. The medical director is responsible for registering the clinic if that clinic is licensed as a health care clinic under ch. 400, F.S. Otherwise, a pain–management clinic must designate a physician who is licensed as a medical physician or osteopathic physician upon registration to be responsible for complying with all requirements related to registering the clinic.

The Board of Medicine and the Board of Osteopathic Medicine are required to adopt rules related to the standards of practice for physicians practicing in privately owned pain–management clinics that primarily engage in the treatment of pain by prescribing or dispensing controlled substance medications. The rules are required to address, minimally, the following subjects: facility operations, physical operations, infection control, health and safety requirements, quality assurance, patient records, training requirements for health care practitioners who are not regulated by another board, inspections, and data collection and

[2] ss. 458.309(4) and 459.005(3), F.S.
[3] See the Department of Health Committee substitute Analysis, Economic Statement and Fiscal Note for SB 2722, dated 3/10/2010, on file with the Senate Health Regulation Committee.
[4] s. 24, ch. 2009-223, L.O.F.
[5] Ibid 2.

reporting. Both boards are actively engaged in the rulemaking process.[6] Currently, Rule 64B8-9.013, F.A.C., and Rule 64B15-14.005, both related to Standards for the Use of Controlled Substances for the Treatment of Pain, apply to all physicians subject to the Board of Medicine and the Board of Osteopathic Medicine, respectively. These rules have been in place for several years.

The Department is required to inspect each pain–management clinic annually to ensure that it complies with the rules adopted by the applicable boards related to the standards of practice for physicians practicing in privately owned pain–management clinics that primarily engage in the treatment of pain by prescribing or dispensing controlled substance medications, unless the office is accredited by a nationally recognized accrediting agency approved by the respective board.

Controlled Substances

Chapter 893, F.S., sets forth the Florida Comprehensive Drug Abuse Prevention and Control Act. The chapter classifies controlled substances into five schedules in order to regulate the manufacture, distribution, preparation, and dispensing of the substances. Substances in Schedule I have a high potential for abuse and have no currently accepted medical use in the United States. Schedule II drugs have a high potential for abuse and a severely restricted medical use. Cocaine and morphine are examples of Schedule II drugs. Schedule III controlled substances have less potential for abuse than Schedule I or Schedule II substances and have some accepted medical use. Substances listed in Schedule III include anabolic steroids, codeine, and derivatives of barbituric acid. Schedule IV and Schedule V substances have a low potential for abuse, compared to substances in Schedules I, II, and III, and currently have accepted medical use. Substances in Schedule IV include phenobarbital, librium, and valium. Substances in Schedule V include certain stimulants and narcotic compounds.

A prescription for a controlled substance listed in Schedule II may be dispensed only upon a written prescription of a practitioner, except that in an emergency situation, as defined by the Department rule, it may be dispensed upon oral prescription but is limited to a 72-hour supply. A prescription for a controlled substance listed in Schedule II may not be refilled.[7] A pharmacist may not dispense more than a 30-day supply of a controlled substance listed in Schedule III upon an oral prescription issued in this state.[8] Currently federal law does not authorize electronic prescribing (e-prescribing) for controlled substances.[9]

Dispensing, Prescribing, and Administering

"Dispense" means the transfer of possession of one or more doses of a medicinal drug by a pharmacist or other licensed practitioner to the ultimate consumer thereof or to one who

[6] See for example, the notices published on January 15, 2010 in the Florida Administrative Weekly for meetings / workshops in February 2010, for each board.
[7] s. 893.04(1)(f), F.S.
[8] s. 893.04(2)(e), F.S.
[9] The federal DEA published proposed rules that would allow practitioners to issue e-Prescriptions for controlled substances; however, these rules have not become final. See Electronic Prescriptions for Controlled Substances, 73 FR page 36722, dated June 27, 2008, available at: <http://edocket.access.gpo.gov/2008/pdf/E8-14405.pdf> (Last visited on March 24, 2010).

represents that it is his or her intention not to consume or use the same but to transfer the same to the ultimate consumer or user for consumption by the ultimate consumer or user.[10]

Prescribing is issuing a prescription. For purposes of this committee substitute, a "prescription" includes an order for drugs that is written, signed, or transmitted by word of mouth, telephone, telegram, or other means of communication by a practitioner licensed by the laws of the state to prescribe such drugs, issued in good faith and in the course of professional practice, intended to be filled or dispensed by another person licensed to do so.[11]

"Administer," for purposes of this committee substitute, means the direct application of a controlled substance, whether by injection, inhalation, ingestion, or any other means, to the body of a person.[12]

Dispensing Practitioner

Chapter 465, F.S., related to the practice of pharmacy, contains the provisions for a dispensing practitioner.[13] Under this law, a practitioner authorized by law to prescribe drugs may dispense those drugs to his or her patients in the regular course of his or her practice. If a practitioner intends to dispense drugs for human consumption for a fee or remuneration of any kind, the practitioner must register with his or her professional licensing board as a dispensing practitioner, comply with and be subject to all laws and rules applicable to pharmacists and pharmacies, and give the patient a written prescription and advise the patient that the prescription may be filled in the practitioner's office or at any pharmacy.

Practitioners in Florida who are authorized to prescribe include medical physicians, physician assistants, osteopathic physicians, advanced registered nurse practitioners, podiatrists, naturopathic physicians, dentists, and veterinarians. However, s. 893.02, F.S., in the controlled substances act, defines which practitioners may prescribe a controlled substance under Florida law. A "practitioner" is defined to mean a licensed medical physician, dentist, veterinarian, osteopathic physician, naturopathic physician, or podiatrist, if such practitioner holds a valid federal controlled substance registry number. Accordingly, the prescribing of controlled substances is a privilege that is separate from the regulation of the practice of the prescribing practitioner.

Board Certification

Section 458.3312, F.S., provides that a physician may not hold himself or herself out as a board–certified specialist unless the physician has received formal recognition as a specialist from a specialty board of the American Board of Medical Specialties (ABMS) or other recognizing agency that has been approved by the Board. Section 459.0152, F.S., provides similar requirements for osteopathic physicians. The Board of Medicine has approved the American Board of Pain Medicine as a recognizing agency.[14] According to the Department, this is the only organization granting board certification in pain medicine, although other organizations grant a

[10] s. 893.02(7), F.S.
[11] s. 893.02(20), F.S.
[12] s. 893.02(1), F.S.
[13] s. 465.0276, F.S.
[14] See Rule 64B8-11.001, F.A.C.

subspecialty in pain medicine.[15] The Department estimates the number of Florida physicians with a board certification or a subspecialty in pain medicine is about 700.

Access to Records without Subpoena or Consent

In Florida, patients have a constitutional right to privacy under Article I, Section 23 of the State Constitution, and judicial decisions. Although Florida courts have recognized patients' rights to secure the confidentiality of their health information (medical records) under the right to privacy under the State Constitution, that right must be balanced with and yields to any compelling state interest. Several statutes authorize the release of patient records without consent of the person to whom they pertain. [16]

Section 893.07, F.S., requires any person who dispenses controlled substances to make and maintain records, including prescription records, related to the receipt and disposition of the controlled substances. The record of all controlled substances sold, administered, dispensed, or otherwise disposed of shall show the:

- Date of selling, administering, or dispensing;
- Correct name and address of the person to whom or for whose use, or the owner and species of animal for which, sold, administered, or dispensed; and
- Kind and quantity of controlled substances sold, administered, or dispensed.

This section of law further provides that the records are to be kept and made available for a period of at least 2 years for inspection and copying by law enforcement officers whose duty it is to enforce the laws of this state relating to controlled substances.

As recently as November 30, 2009, the First District Court of Appeal upheld this statute. The court held[17] that this statute does not require a subpoena, warrant, or prior notice to the patient; and provision of records to law enforcement in compliance with state law did not violate the federal Health Insurance Portability and Accountability Act and did not violate the defendant's state constitutional right to privacy.

Health Care Clinic License

Certain health care clinics are licensed and regulated by the Agency for Health Care Administration (Agency) under part X of ch. 400, F.S., the Health Care Clinic Act (Act). A clinic is defined as an entity at which health care services are provided to individuals and which tenders charges for reimbursement for such services, including a mobile clinic and a portable equipment provider.[18] However, the Act provides for numerous exceptions to the requirement for licensure and compliance with regulation under the Act.

Every entity that meets the definition of a "clinic" must maintain a valid license with the Agency at all times, and each clinic location must be licensed separately. Licenses are issued for a 2-year period at a fee of $2,000. The application for licensure must include: information regarding the identity of the owners, the financial officer or similarly situated person, licensed health care

[15] Ibid 3.
[16] See for example, s. 395.3025(4), F.S., related to patient records in hospitals and s. 456.057, F.S., related to patient records held by health care practitioners.
[17] See *State of Florida v. Cathy L. Carter*, 23 So.3d 798, (Fla. 1st DCA 2009), 34 Fla. L. Weekly D2466.
[18] s. 400.9905(4), F.S.

practitioners at the clinic, and the medical director or clinic director; proof of financial ability to operate a clinic; any exclusions, permanent suspensions, or terminations from the Medicare or Medicaid programs; and proof that the clinic is in compliance with applicable rules. A level 2 background screening pursuant to ch. 435, F.S., is required of each of the persons identified in the application for clinic licensure and a license may not be granted to the clinic if any of these persons has been found guilty of, regardless of adjudication, or has entered a plea of nolo contendere or guilty to any offense prohibited under the level 2 standards for screening or a violation of insurance fraud under s. 817.234, F.S., within the past 5 years.

III. Effect of Proposed Changes:

Section 1. Amends s. 456.037, F.S., to provide that a pain–management clinic that is required to be registered is a business entity for purposes of regulation by the Division of Medical Quality Assurance in the Department.

The committee substitute requires a licensee who is authorized to prescribe controlled substances and practices at a pain–management clinic to be responsible for maintaining the control and security of his or her prescription blanks and any other methods used for prescribing controlled substance pain medication. The licensee is required to notify the Department in writing, within 24 hours following any theft or loss of a prescription blank or breach of any other method for prescribing pain medication. The licensee is also required to comply with the requirements for counterfeit-resistant prescription blanks in the Florida controlled substances act and the related rules.

The licensee is required to notify the applicable board of the date of termination of employment within 10 days after terminating his or her employment with a pain–management clinic.

(See comments under Technical Deficiencies)

Section 2. Amends s. 456.057, F.S., to provide an exception to the requirement concerning a patient's release for his or her patient records. The Department is not required to attempt to obtain a patient release when investigating an offense involving the inappropriate prescribing, overprescribing, or diversion of controlled substances and the offense involves a pain–management clinic. This section of law retains the requirement for obtaining patient records pursuant to a subpoena.

Section 3. Amends s. 456.069, F.S., to authorize the Department to inspect, at all reasonable hours, any facility offering services that require the facility to be registered as a pain–management clinic. (See comment under Technical Deficiencies related to lines 258 – 260.)

As a part of inspecting, the Department is currently authorized to obtain evidence. This committee substitute adds that the evidence may include, but is not limited to, patient records. The committee substitute authorizes the Department to obtain patient records without patient authorization or subpoena from any pain–management clinic required to be licensed, if the Department has probable cause to believe that a violation is occurring, reasonably believes that obtaining authorization is not feasible because of the volume of activity and reasonably believes that obtaining authorization or a subpoena would jeopardize the investigation.

Section 4. Amends s. 456.071, F.S., to provide that venue for a challenge to, and enforcement of, subpoenas and orders authorized under the general provisions related to health professions and occupations is in the Circuit Court for the Second Judicial Circuit (Franklin, Jefferson, Gadsden, Leon, Liberty and Wakulla Counties), in the county where the examination, investigation, or hearing is conducted, or in the county in which the person resides.

Section 5. Amends s. 456.072, F.S., to add grounds for which disciplinary action may be taken against a licensee who serves as the medical director or the designated physician of a pain–management clinic.

Sections 6 and 9. Amend s. 458.309, F.S., related to rulemaking by the Board of Medicine, and s. 459.005, F.S., related to rulemaking by the Board of Osteopathic Medicine, to clarify that the requirement for pain–management clinics to register is an ongoing requirement and to provide that the Department's inspection of a pain–management clinic must include a review of patient records.

As a part of registration, all pain management clinics must identify a designated physician who has a full, active, and unencumbered license to be responsible for complying with all requirements related to registration of the clinic.

The committee substitute adds disciplinary actions that the Department may take against a pain–management clinic, including denying an application, revoking or suspending a registration, or imposing an administrative fine. The committee substitute provides factors that the Department must consider when determining whether a penalty is to be imposed and in fixing the amount of a fine.

The committee substitute requires any corrective action undertaken to be documented in writing by the owner or designated physician and verified by the Department on follow-up visits. The Department is authorized to impose a fine, and for an owner-operated pain–management clinic, revoke or deny a clinic registration if the designated physician knowingly and intentionally misrepresents actions taken to correct a violation.

An owner or designated physician of a pain–management clinic who concurrently operates an unregistered pain–management clinic is subject to an administrative fine of $5,000 per day. Any pain–management clinic whose owner fails to apply for a change of ownership registration and operates the clinic is subject to a $5,000 fine.

During an onsite inspection, the Department is required to make a reasonable attempt to discuss each violation with the owner or designated physician of a pain–management clinic before issuing a formal written notification.

If the registration of a pain–management clinic is revoked or suspended, certain specified parties are required to cease operating the facility as a pain–management clinic, remove all signs and symbols identifying the premises as a pain–management clinic, and advise the Department of the disposition of the medicinal drugs located on the premises. Medicinal drugs that are purchased or

held by a pain–management clinic that is not registered may be deemed adulterated under the Florida Drug and Cosmetic Act.

If the registration of a pain–management clinic is revoked, any person named in the clinic registration documents may not, individually or as part of a group, apply to register a pain–management clinic for five years after the date of revocation. The Department may determine the period of suspension for the registration of a pain–management clinic, not to exceed one year.

Additional exemptions are provided to the requirement to register a pain–management clinic. These include a clinic that: is owned by a publicly held corporation, is affiliated with an accredited medical school, does not prescribe or dispense controlled substances for the treatment of pain, or is owned by a corporate entity which is exempt from federal taxation as a charitable organization.

The Department is required to adopt rules:

- That are necessary to administer the registration and inspection of pain–management clinics. These rules must establish the specific requirements, procedures, forms, and fees; and
- Defining what constitutes practice by a designated physician at the office location for which the physician has assumed responsibility as the designated physician for a pain–management clinic. The Department is provided with factors to consider when adopting this rule.

The Boards of Medicine and Osteopathic Medicine are required to adopt a rule establishing the maximum number of prescriptions for Schedule II or Schedule III controlled substances that may be written at any one registered pain–management clinic during a 24-hour period.

(See the comments under Technical Deficiencies)

Sections 7 and 10. Create s. 458.3265, F.S., related to pain–management clinics under the practice of medicine, and s. 459.0137, F.S., related to pain–management clinics under the practice of osteopathic medicine. A medical physician and osteopathic physician are prohibited from practicing medicine or osteopathic medicine in a pain–management clinic:

- Unless, effective July 1, 2012, the medical physician or osteopathic physician has completed a pain medicine fellowship or pain medicine residency, or is a pain medicine specialist registered with and qualified by the appropriate board; or
- If the pain–management clinic is not registered as required by s. 458.309 or s. 459.005, F.S.

If a pain–management clinic fails an annual inspection, the Department may revoke the clinic's certificate of registration and prohibit all physicians associated with the pain–management clinic from practicing at that location. (See comment under Technical Deficiencies) A physician who violates these provisions is subject to review by his or her appropriate medical regulatory board.

The Department is required to deny the registration of a pain-management clinic:

- That is not fully owned by a physician or group of physicians licensed under ch. 458, F.S., or ch. 459, F.S., or a health care clinic licensed under part X of ch. 400;
- That is owned by or has any contractual or employment relationship with a physician:
  - Whose DEA license has ever been revoked,

- Whose application for a license to prescribe, dispense, or administer a controlled substance has been denied by any jurisdiction, or
- Who has been convicted of, or has entered a plea of guilty or nolo contendere to, regardless of adjudication, an offense that constitutes a felony for receipt of illicit and diverted drugs, including a controlled substance listed in Schedule I, Schedule II, Schedule III, Schedule IV, or Schedule V, in this state, any other state, or the United States.

If the Department finds that a pain–management clinic is owned, directly or indirectly, by a person with one of the disqualifying conditions identified above, the Department must deny registration or revoke a previously issued registration certificate. The Department is authorized to grant an exemption to the ownership restrictions if more than 10 years have elapsed since adjudication.

Only a medical physician or an osteopathic physician may dispense any medication, including a controlled substance, on the premises of a pain–management clinic.

The committee substitute imposes requirements concerning a physician examination of a patient and documenting in a patient's record the reasons for prescribing or dispensing more than a 72-hour dose of a controlled substance for the treatment of chronic nonmalignant pain. (See the comments under Technical Deficiencies related to lines 618 – 622 and 933 – 937.)

Sections 8 and 11. Amend s. 458.327, F.S., related to the practice of medicine, and s. 459.013, F.S., related to the practice of osteopathic medicine, to add that knowingly operating, owning, or managing a non-registered pain–management clinic that is required to be registered is a felony of the third degree. Knowingly prescribing or dispensing, or causing to be prescribed or dispensed, controlled substances in a non-registered pain–management clinic that is required to be registered is a misdemeanor of the first degree.

Section 13. Provides an effective date of July 1, 2010.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this committee substitute have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of this committee substitute have no impact on public records or open meetings issues under the requirements of Article I, Section 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this committee substitute have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

D. Other Constitutional Issues:

Article III, Section 6 of the Florida Constitution requires every law to embrace but one subject and matter properly connected therewith, and the subject must be briefly expressed in the title. This committee substitute is an act relating to pain management, but section 4 of the committee substitute addresses setting venue for challenges to, and enforcement of, subpoenas and orders related to all health professions and occupations subject to ch. 456, F.S.

Article I, Section 23 of the State Constitution provides for an individual's right to privacy. This right has been extended to medical records although there are numerous exceptions where patient consent for the release of the records is not required.[19] These exceptions are generally based upon a compelling state interest in providing for the release without a patient's consent and authorization. This committee substitute provides exceptions to requiring patient consent for the Department to access patient records in pain–management clinics.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Due to the restrictions on ownership and registration, this committee substitute will impact the ability of some people to own and operate a pain–management clinic. Patient records concerning services and medications received through pain–management clinics might be more readily available to the Department without the judicial scrutiny afforded by the requirement to obtain a subpoena prior to accessing the patient records.

C. Government Sector Impact:

The Department indicated the bill as originally filed would have a fiscal impact on it due to the increased workload associated with some of the provisions in it. Most of those provisions are no longer included in the committee substitute. At this time, the fiscal impact to the Department for the committee substitute is not known.

VI. Technical Deficiencies:

Section 1. Lines 173 – 187 require a professional licensee to comply with certain provisions. However, these requirements are included within a section of law related to business establishments. It might be beneficial to move these requirements into sections of law that specifically address activities required for professionals. Additionally, the provisions within this subsection refer to a pain–management clinic and it is not apparent whether the requirements apply to all pain–management clinics or only those that are required to be registered.

[19] Ibid 16.

Lines 177 – 180 require a licensee to comply with the requirements for counterfeit-resistant prescription blanks in s. 893.065, F.S., and the rules adopted pursuant to that section. The use of counterfeit-resistant prescription blanks is not required. Both s. 893.065, F.S., and the administrative rule make the use optional. It is not apparent what requirement is imposed on a licensee in these lines of this committee substitute.

Section 3. Lines 258 – 260 appear to duplicate the authority granted to the Department in the preceding paragraph, which authorizes the Department to inspect any establishment at which the services of a licensee authorized to prescribe controlled substances specified in ch. 893, F.S., are offered.

Sections 6 and 9 amend the sections of law authorizing the Board of Medicine and the Board of Osteopathic Medicine to adopt rules. Most of the provisions, existing and new, in these two sections related to pain–management clinics could more appropriately be moved to Section 7 and Section 10 of the committee substitute creating ss. 458.3265, F.S., and 459.0137, F.S., related to pain–management clinics under the practice of medicine and osteopathic medicine, respectively.

Lines 434 and 793 address a factor that the DOH is to consider when determining whether to impose a penalty against a pain–management clinic. The use of the term "licensee" is not clear. It could refer to the pain–management clinic, which is registered not licensed; a licensed medical or osteopathic physician working at the pain–management clinic; or some other licensed person working at the pain–management clinic.

Lines 444 – 445 and 803 – 804. The meaning of the phrase "date fixed for termination" is unclear.

Lines 491 – 492 and 850 – 851 need clarification, perhaps: The period of suspension for a pain–management clinic registration shall be prescribed by the Department, but may not exceed one year.

Line 547 references subsections (3) and (4). Probably the reference should be to subsection (4).
Line 859 references subsections (3) and (4). Probably the reference should be to subsection (3).

Line 553. Including the Board of Osteopathic Medicine in this rulemaking requirement is redundant since a similar requirement is imposed under ch. 459, F.S., related to osteopathic medicine. Likewise, on line 865, it is redundant to include the Board of Medicine in this section.

Sections 7 and 10. The sentences beginning on line 571 and 886 that require each location of a pain–management clinic to be registered separately is redundant to the identical statement on line 399 in s. 458.309(4), F.S., and line 711 in s. 459.005, F.S.

Line 578. The phrase related to prohibiting all physicians from practicing at a pain–management clinic with a revoked registration is redundant to other provisions, see for example line 570 that prohibit a physician from practicing medicine in an unregistered pain–management clinic.

Lines 618 – 622 and 933 – 937. The intent and requirements in these lines is not clear and they should be rewritten. It is unclear whether the requirement is a physical examination of each patient on the day in which a controlled substance is dispensed, or this is required only when the physician *prescribes* or dispenses more than a 72-hour dose.

VII. Related Issues:

None.

VIII. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:
(Summarizing differences between the Committee Substitute and the prior version of the committee substitute.)

CS by Health Regulation on March 26, 2010:

- Eliminates the continuing education requirement related to controlled substances;
- Revises the authority for the DOH to obtain patient records from a pain-management clinic without patient authorization or a subpoena;
- Deletes the grounds for disciplinary action against a designated physician for a registration obtained through an error of the DOH or board;
- Removes references to a medical director;
- Provides additional exceptions to the clinic registration requirement;
- Requires the Boards of Medicine and Osteopathic Medicine to adopt a rule establishing the maximum number of prescriptions that may be written at a clinic daily;
- Effective July 1, 2012, requires any physician or osteopathic physician to have completed a pain medicine fellowship, pain medicine residency, or be a pain medicine specialist to practice in a pain-management clinic;
- Requires a pain-management clinic to be owned by a physician licensed under ch. 458 or ch. 459, F.S., group of physicians, or licensed as a health care clinic;
- Revises the disqualifying offenses or conditions for ownership;
- Eliminates the requirements for the owner, operator, or designated physician to be onsite for a certain period and review patient files;
- Eliminates the provision listing a pharmacist as an authorized dispenser;
- Eliminates the requirement that a physician follow the DOH's rule for treating pain; and
- Eliminates the new licensure / renewal scheme including the fingerprinting requirements.

B. Amendments:

None.